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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/929,665	08/13/2001	Neil H. Bander	266/187	9976

26161 7590 04/20/2005

FISH & RICHARDSON PC
225 FRANKLIN ST
BOSTON, MA 02110

EXAMINER

NICKOL, GARY B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	09/929,665	BANDER, NEIL H.	
	Examiner	Art Unit	
	Gary B. Nickol Ph.D.	1642	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 18 March 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 26 November 2004. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☒ Applicant's reply has overcome the following rejection(s): 35 USC 101 & obvious double patenting.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: _____

Claim(s) rejected: 144, 156-168, 170-210.

Claim(s) withdrawn from consideration: _____

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).


10. ☒ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Attached.

12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____

13. ☒ Other: Attachment.


GARY NICKOL
PRIMARY EXAMINER

Gary B. Nickol Ph.D.
 Primary Examiner
 Art Unit: 1642

Art Unit: 1642

Re: Bander, N.

Date of priority: 05-06-1996

Response to Amendment

The Amendment filed 03-18-2005 in response to the Office Action of 05-20-2004 is acknowledged and has been entered.

Claims 144, 156-168, 170- 210 are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Rejection Maintained:

Claims 144, 156-168, and 170- 210 are rejected and/or remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons of record and for the reasons set forth below.

As set forth previously, the disclosure fails to provide a written description for an isolated antibody that “**competes for binding**” to PSMA (prostate specific membrane antigen) with a

Art Unit: 1642

monoclonal antibody selected from the group consisting of an E99, a J415, a J533 and a J591 monoclonal antibody. Thus, the claimed subject matter constitutes new matter.

Applicants argue (Response, page 13) that the written description requirement is met if the specification shows that an applicant was in possession of the claimed invention at the time of filing. Applicants further refer to several court decisions: *in Re Smith, Purdue Pharma v. Faulding, Inc.*, and *In re Wright* which, taken out of context, appear to conclude that the original disclosure need not provide literal support or exact wording for claimed subject matter. In this particular instance, applicants note that the claimed invention involves a method that uses an antibody having a specific feature: “it competes for binding PSMA with a specific, disclosed antibody, namely E99, J591, J415, or J533”. Applicants further provided a Declaration by Abbie Celniker under 37 CFR 1.132 which proposes that the specification, on page 27, lines 26-35, indicates that Applicant was in *possession* of antibodies that compete for binding with J415, J591, J533 or E99.

Applicant’s arguments and the Declaration have been carefully considered, but are not found persuasive. As set forth previously, the specification only provides a written description and indicates possession of a genus of antibodies that bind to the extracellular domain of PSMA and four such monoclonal antibodies, or *species* of the genus, e.g. E99, J591, J415, or J533.

The rejected claims, (i.e. those covering a class of antibodies that “compete for binding” to E99, J591, J415, or J533) are not representative of the above genus or species. In particular, competing antibodies represent those antibodies that have yet to be discovered and that comprise the same binding properties as E99, J591, J415, or J533. It is applicant’s contention that they are in possession of all such competing antibodies from the paragraph on page 27, lines 26-35 (*note*

Art Unit: 1642

to applicant-- this passage appears to be on page 32, lines 28+) in the disclosure which refers to the conjugation of drugs to antibodies. This argument has been considered but is not found persuasive, as it appears that the alleged support has been taken out of context. The passage that applicants refer to pertains to biological agents conjugated to prodrugs- such as antibody conjugates. Prodrugs are inactive drugs. In the instant case, the conjugated prodrug becomes activated (page 32, line 34) “only when in *close* proximity with a prodrug activator”. Thus, the fact that a preferred embodiment of a prodrug/prodrug activator scenario is one in which the biological agent binds in close proximity to one another (i.e...to non-competing sites) on the antigen is *not* surprising given the fact that said activators must be nearby to activate the prodrug. In contrast, however, it would be surprising and quite complex to conceive of administering biological agents conjugated to prodrugs and or prodrug activators that bind to *competing* sites on an antigen because such sites are indicative of the same epitope. Hence, the administration of biological agents (for the purposes of activating a prodrug) that bind to competing sites would effectively reduce the probability that a prodrug would be activated. Thus, applicants alleged support for the inclusion of “competing” sites is not found persuasive because there is no contextual nexus that adequately provides support for the newly amended claims. The fact that one mechanism of binding is preferred does not necessarily provide possession for a completely different functional and mechanistic effect, i.e. competing antibodies. This reasoning further extends to applicants arguments (Response, page 14) that the specification discloses what constitutes a competing site and what constitutes a non-competing site by stating that “whether two biological agents bind to competing or non-competing sites can be determined by conventional competition binding assays.”. Again, such a passage refers to the administration of

Art Unit: 1642

non-competing antibodies wherein the next sentence (page 33, line 3) recites: "Thus, for example, the first biological agent can be one of J591, J533, and E99, and the second biological agent can be J415. Alternatively, the first biological agent can be J415, and the second biological agent can be one of J591, J533, and E99." Thus, there is never a suggestion or a contemplation to possess or use antibodies that recognize the same epitope or compete with E99, J415, J533 and J591. Hence, applicants appear to be claiming a subgenus of antibodies not supported nor contemplated by the specification as originally filed. It is noted that a generic or a sub-generic disclosure cannot support a species unless the species is specifically described. It cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. See In re Smith 173 USPQ 679, 683 (CCPA 1972) and MPEP 2163.05. Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

All other rejections and or objections are withdrawn in view of applicant's amendments and arguments there to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 571-272-0835. The examiner can normally be reached on M-Th, 8:30-5:30; alternate Fri., 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1642

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary B. Nickol Ph.D.
Primary Examiner
Art Unit 1642

GBN


GARY NICKOL
PRIMARY EXAMINER